REMARKS

Status of the Claims

Claims 1-6,12-16, and 21-22 are rejected under 35 U.S.C., 112, first paragraph.

Claims 1-5, 7-8 and 10, 14, 18 and 21-22 are rejected under 35 U.S.C. 103(a).

Claim 17 is objected to.

Amendments

Basis for the present amendments can be found in the original claims and throughout the examples as originally filed. No new matter has been added, nor has the scope of the claims been broadened by these amendments.

Restriction Requirement

In the previous amendment Applicants confirmed (with traverse) the election of the invention of group II, and amended their claims consistent with the election. (See Amendment dated September 5, 2003). In paragraph two of the office action mailed on November 28, 2003, the Examiner contends that the election does not include any spiro compounds (wherein R8 and R9 form a ring) because "the elected invention are the species of claims 16-17 which does not include any spiro compounds. . ." Applicants traverse.

Applicants elected the invention of claim 2, 16-17 and generic claims 1, 3-8, 10-15, 18 and 21-22 reading on claim 2 compounds. (See Detailed Action dated May 12, 2003 and Amendment dated September 5, 2003). Accordingly, Applicants elected the compounds of claim 2 and 16, not merely the species of claim 17. Please note, even if Applicants had narrowed their election to the individual compounds of claim 17, once the Examiner had found these individual compounds novel, Applicants expected the search/examination to have been extended to the wider scope of claims 2 and 16, both of which include spiro compounds ("wherein R_8 and R_9 taken together form a monocyclic or bicyclic cycloalkyl or heterocyclo joined in a spiro fashion to the piperidine ring").

Applicants do not believe the Examiner may unilaterally narrow Applicants' election. Accordingly, Applicants request that the Examiner search and examine the scope of the entire election.

Rejections under U.S.C 112

With the exception of acylated amino functionalities, the Examiner rejected claims 1-6 and 12-16 for lack of enablement contending that the term "prodrug" can cover from a "a single acylation to a convoluted preparation such as prolong release targeted conjugate, etc." The Examiner has reasserted this rejection. In order to expedite prosecution, Applicants have amended the claims to delete the term "prodrug."

With respect to the rejection based on the term "wherein two. . . are joined to form a fused ring", as discussed in the previous amendment, Applicants believe that ample information is given in the Specification to enable one of skill in the art to identify appropriate starting materials. Applicants do not understand the Examiner's rejection that "[o]ne skilled in the art may be able to make the compounds *if one knows what it is*".

Applicants are also at a loss as to why the Examiner refers in particular to "R13-R14 or R14-R15 forms a fused ring." In the instant claim 1, it is specified that ". . .R_{13} and R_{14} or R_{14} and R_{15} may join together to form a heterocyclo or heteroaryl, . . ." From the specification it is clear that a heterocyclo or heteroaryl group may be bicyclic or tricyclic system which includes a fused ring. (See th Specification, page 12, lines 19-27). A fused ring is, by definition, a ring that shares more than one atom in common with another ring. Further, contrary to the Examiner's contention that compounds having fused rings are not exemplified, the Examiner's attention is directed to Examples 21, 24, and 29. Applicants again request withdrawal of the 112 rejection of the term "wherein two . . . are joined to form a fused ring" or clarification from the Examiner as to the nature of the rejection.

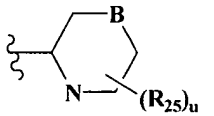
The Examiner has maintained the rejection of claims 21-22 under 35 USC 112 in spite of Applicants amending the claims in response to her rejection. The Examiner has then imposed a new rejection under 35 U.S.C. 101 with respect to the phrase "treating a melanocortin receptor associated condition". The Examiner contends that the claim is confusing as to whether the method is on receptor function or on treating a disorder and states that "mere manipulation without effect is not within the scope of "use". Applicants traverse.

As stated in the Specification, page 43, lines 16-19, "the inventive compounds exemplified herein ha[ve] been tested and show activity at a measurable level for modulating a melanocortin receptor according to an assay described below and/or an assay known in the field, such as, for example, assays described in WO 00/74679 and WO 01/91752." Credible (recognized in the art) utilities for compounds that modulate melancortin receptors are cited the in the Specification, pages 34 through paragraph one on page 37. Accordingly, Applicants request withdrawal of the new rejection under 35 U.S.C. 101.

Also, as evidenced in the many references cited throughout the Specification, it is well known in the art that melanocortin receptor associated conditions may be treated by compounds which modulate melanocortin receptors, such as those of the present invention. Accordingly, Applicants assert that based on what is known in the art and the information given in the specification, one of skill in may treat melanocortin receptor associated conditions.

Rejections under 35 U.S.C. 102(a)

The Examiner alleges that the rejection of Claims 1-2, 4-5, 10, 14, 18 and 21-22 under 35 U.S.C. 102(e) over Palucki has been dropped in view of the amendment requiring that y is at least 1. Applicants want to emphasize that the variable "y" has NOT been so amended.

However, Applicants have amended the claims so that W does not include 

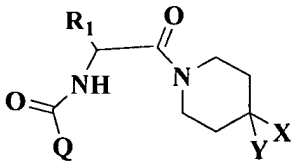
, wherein B is N, O or S. Basis can be found in throughout the examples. Applicants believe that the claims, as now amended, renders the rejection for anticipation over Palucki moot.

Rejections under 35 U.S.C. 103(a)

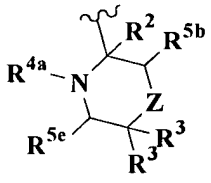
The Examiner has maintained the rejection of Claims 1-2, 4-5, 10, 14, 18 and 21-22 under 35 U.S.C. U.S.C. 103(a), as being obvious over US 6,458,790 ("Palucki") for the "reasons of record" recommending that the claims be amended to maintain consistency in the y variable (i.e. y is at least 1). The Examiner further contends that "to the extend that y is at least 1, then the claims are still drawn to the 1-methylene inserted compounds of the prior art which are considered structural prima facie in absence of unexpected result"

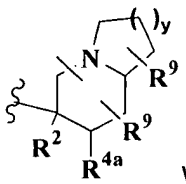
First, as discussed above, "y" has not been amended in the claims. The "y" variable definition is consistent in claim 1. There is merely a proviso in the definition of R_{11} in which R_{11} is not heterocyclo or heterocycloalkyl when y is 0.

Secondly, Applicants amended claims describe compounds that are not simply a 1-methylene inserted variation of the Palucki compounds. Palucki's compounds are represented by the following generic structure:



where Q is a heterocyclo ring having the specific core structure



or


where Z is O, S or NR (See Palucki, column 5, lines 58-65).

None of Applicants' amended claims contain the heterocyclo rings described by the Q variable of the Palucki compounds. Nor does Palucki describe or suggest the unexpected desirability of Applicants' claimed compounds. Palucki actually teaches away from Applicants claimed compounds as one of skill in the art would only expect desirable activity from compounds

having the aforementioned Q group heterocycles. Moreover, Palucki specifies that their particularly described heterocycles be directly attached to a carbonyl. Applicants claimed compounds are substantially different than the Palucki compounds as they do not include the Palucki heterocycles ("Q), nor do they describe any heterocycle directly attached to the carbonyl. Accordingly, Applicants request withdrawal of the obviousness rejection under 35 U.S.C.§ 103(a) over Palucki.

The Examiner again rejected claims 1-5, 7-8, and 10-16 under 35 U.S.C. §103(a) over US 5,622,973 ("Morriello") in view of US 6,303,620 ("Hansen") for the "reasons of record". Applicants ask the Examiner to reconsider this rejection.

Both Morriello and Hansen teach compounds having growth hormone secretage ("GSH") activity useful in the treatment of growth-associated disorders. One of skill in the art of melanocortin receptor activity would not look to the structural variation of GSH compounds in order to design compounds having melanocortin receptor activity. In other words, there is no motivation nor expectation of success by one of skill in the art to design compounds having melanocortin activity simply based on the structural isomerism compounds known to have GSH activity. Accordingly, Applicants' compounds are not obvious over Morriello in view of Hanson and it is requested that the Examiner's rejection of claims 1-5, 7-8, and 10-16 under 35 U.S.C. 103(a) be withdrawn.

Objections

Claim 17 has been drafted in independent form. Applicants believe the claim is now in condition for allowance.

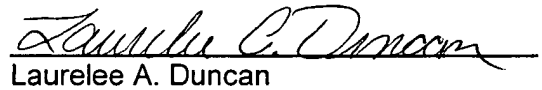
Summary

The Applicants believe the claims, as amended, are now in condition for allowance. The Examiner is invited to contact the undersigned by telephone, at the number listed below, if it is believed that a telephonic communication would facilitate the prosecution of this application.

FEES

No fees should be due. However, if it is determined that a fee is due, please charge same to Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

Respectfully submitted,



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